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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,300	09/13/2001	Helmut Eckert	0147-0229P	2392

2292 7590 06/03/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/03/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,300

Applicant(s)

ECKERT ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 8/13/2002 (paper no. 9) is acknowledged and entered into the record. Accordingly, claims 10-14 are newly added.
2. Therefore, claims, 1-14 are pending and examined on the merits.

Claim Rejections Withdrawn - 35 USC § 112, 2nd paragraph

3. The rejection of claim 5-6 under 35 USC 112, 2nd paragraph as being indefinite is withdrawn in view of the amendments set forth by the applicant.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claim 6 under 35 USC 112, 1st paragraph as lacking enablement is maintained for the reasons of record. Applicant argues that the specification provides guidance so that one of skill would be able to make and use the instant invention because it discloses other types of TAAs that could potentially be used as targets. Applicant further states that a declaration filed by Dr. Loibner presents supplemental information that would provide evidence that the claimed invention is enabled. Applicant's arguments have been carefully considered but are not found persuasive. First, the specification has only prophetically disclosed the use of other antibodies, the working examples (although not limited in scope by the example) only discuss one specific antibody, namely HE2 antibody directed against Ep-Cam. The specification has not taught how to use a composition wherein there are two or more antibodies. One of skill in the art is essentially left to experiment with the instant invention because the specification has not taught which other antibody or antibodies are to be used in the composition. It is also noted that the applicant refers to the Loibner Declaration,

wherein it is alleged that supplemental data for the claimed invention is provided.

However, such a declaration is not present in the case and because the applicant has not provided this information a clear enablement analysis cannot be made.

Furthermore, one of skill in the art would be forced into undue experimentation to practice the instant invention because the antibodies contemplated have not been taught.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 1-9 and now newly added claims 10-14 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the amendment to the claims to recite prevention of metastasis would help clarify the limitations of the claims. Applicant further argues that supplemental information provided by an abstract indicates that "vaccination with pharmaceutical compositions according to the invention decreases circulating tumor cells in cancer patients." Applicant's arguments have been carefully considered but are not found persuasive. The instant specification provides some in vivo data wherein the administration of the HE2 antibody to monkeys generated an anti-idiotypic response. However, the threshold of enablement for vaccines is higher than the analysis of antibody production in the serum of the immunized animal. The specification has not provided any challenge studies wherein subsequent readministration of cancer cells expressing the Ep-Cam antigen would elicit a protective effect. All the specification has shown is the ability to generate antibody response upon initial challenge. As the applicants have stated in their support for enablement, the clinical data has only

provided evidence for the treatment of cancer, wherein there is a "decrease" in the number of cancer cells. There is no indication from the specification that the administration of an antibody composition to a subject would indeed "prevent" the formation of cancer. Therefore, the specification has not enabled a vaccine, but rather has provided data and enablement for a therapeutic composition and treatment method of reducing cancer.

Claim Rejection Maintained - 35 USC § 102

6. The rejection of claims 1-3 under 35 USC 102(a) as being anticipated by Braun *et al* is maintained for the reasons of record. Applicant argues that the certified translation of the priority document would antedate the cited reference. However, no such certified document is present in the instant amendment. Therefore, the claims are still anticipated until the applicant furnishes the certified document.

Claim Rejections Maintained - 35 USC § 103

7. The rejection of claim 7 under 35 USC 103(a) as being obvious over Braun *et al* in view of Pardoll D, is maintained for the reasons of record. Applicant argues that Braun *et al* can be antedated by the filing of the certified priority document (see arguments above, paragraph 6). Applicant also argues that although Pardoll D does teach the use of cancer vaccines with adjuvants, there is no recitation of cellular membrane antigens. Applicant's arguments have been carefully considered but are not found persuasive. The combination of two known products, absent undue experimentation, is considered obvious, because there are no unexpected results present for the combination of the cancer vaccine and the adjuvants.

Conclusion

8. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Application/Control Number: 09/889,300
Art Unit: 1642

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
May 23, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER